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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,079	BEAUDRY ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11 and 28, drawn to nucleic acids, classified in Class 536, subclass 23.5.

II. Claim 12, drawn to proteins, classified in Class 530, subclass 350.

III. Claim 13, drawn to antibodies, classified in Class 530, subclass 387.

IV. Claims 14-18, drawn to methods of diagnosing lung cancer by detecting a polynucleotide, classified in Class 435, subclass 6.

V. Claims 19 and 20, drawn to a method for detecting lung cancer by detecting a compound that binds to a gene, classified in Class 435, subclass 6.

VI. Claims 21 and 22, drawn to methods for detecting lung cancer by identifying an agent that binds to a protein, classified in Class 435, subclass 7.1.

VII. Claims 23, drawn to a computer system with data for the polynucleotides of SEQ ID NO: 1-40, classified in Class 702, subclass 19.

VIII. Claim 24, drawn to a method of detecting lung cancer using a database, classified in Class 702, subclass 19.

IX. Claim 25, drawn to a method of screening databases, classified in Class 702, subclass 19.

X. Claims 26 and 27, drawn to a method of screening for therapeutic agents, classified in Class 435, subclass 6.

XI. Claim 29, drawn to a transgenic animal, classified in Class 800, subclass 13.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and physicochemical properties. Invention I is drawn to nucleic acids whereas invention III is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention II do not require the particular products of the nucleic acids of invention I since the proteins of invention II can be isolated from natural sources or chemically synthesized.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to make the antibodies of invention III. Furthermore, the different inventions are not disclosed as capable of use together and have different functions and have different physical and structural properties.

Inventions I and IV, I and V and I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the

nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions I and VI, and I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to practice the methods of inventions VI or VIII.

Inventions I and VII are drawn to patentably distinct inventions. The nucleic acids of invention I and the computer readable mediums of invention VII have different functions and physical and structural properties. The nucleic acids of invention I are composed of nucleotides linked by phosphodiester bonds, whereas the computer readable mediums of invention VII are composed of data and comprise computer hardware and software for manipulating sequence data digitally. Furthermore, the compositions are utilized in different methodologies, such that the nucleic acids of invention I may be used in hybridization assays or in methods for synthesizing proteins, while the computer readable mediums of invention VII can be used in a storage capacity or may be utilized in methods for searching a databank. The computer readable medium of invention VII does not require the particular nucleic acid molecules of invention I.

Inventions I and IX are drawn to patentably distinct inventions. The nucleic acids of invention I are not required to practice the methods of invention IX. It is noted that the computer readable mediums of invention IX have different functions and physical

and structural properties compared to the nucleic acids of invention I. The nucleic acids of invention I are composed of nucleotides linked by phosphodiester bonds, whereas the computer readable mediums required for invention VII are composed of data and comprise computer hardware and software for manipulating sequence data digitally. Furthermore, the compositions are utilized in different methodologies, such that the nucleic acids of invention I may be used in hybridization assays or in methods for synthesizing proteins, while the computer readable mediums used in the method of invention IX can be used in a storage capacity or may be utilized in methods for searching a databank.

Inventions I and XI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the transgenic animal is a patentably distinct entity over the nucleic acids since the transgenic animal has its own unique functional and structural characteristics. The subcombination has separate utility such as to serve as a template for DNA or RNA synthesis or as a probe in a hybridization assay.

Inventions II and III are patentably distinct in structure in that the proteins of invention III have a different amino acid sequence as compared to the antibodies of invention IV. Furthermore, the products of invention II and III are utilized in different

methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in therapeutic methods. Synthesis of the antibodies of invention III does not require the particular products of the proteins of invention II since the antibodies of invention III can be isolated from natural sources.

Inventions II and IV, II and VIII, II and IX and II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are not required to practice the methods of inventions IV, VIII, IX or X.

Inventions II and V, and II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating or detecting antibodies.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the proteins of invention II are not required for the computer databases of invention VII.

Inventions II and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the proteins of invention III are not required to make the transgenic animal of invention X and the proteins of invention II have unique structural and functional properties distinct from the transgenic animals of invention X.

Inventions III and IV, III and V, III and VIII, III and IX, and III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the methods of invention IV, V, VIII, IX or X.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for therapeutic uses.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required for the computer systems of invention VII.

Inventions III and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to make the transgenic animal of invention XI and the antibodies of invention XI have unique structural and functional properties distinct from the transgenic animals of invention III.

Inventions IV, V, VI, VIII, IX and X are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to distinct methods, each requiring different reagents, involving different method steps and having different objectives.

Inventions VII and IV, VII and V, VII and VI, VII and X are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions In the instant case, the different inventions are not disclosed as capable of

use together because the nucleic computer system of invention VII are not required to practice the methods of inventions IV, V, VI, or X.

Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the computer systems of invention VII can be used in a materially different process, such as for identifying and characterizing novel gene sequences.

Inventions VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the computer systems of invention VII can be used in a materially different process, such as for diagnostic purposes.

Inventions XI and IV, XI and V, XI and VI, XI and VIII, XI and IX and XI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the transgenic animals

of invention XI are not required to practice the methods of inventions IV, V, VI, VIII, IX, or X.

Sequence Election Requirement Applicable to Groups I-IV and VI-XI

3. The claims have been presented in improper Markush format, as distinct products and distinct methods are improperly joined by the claims. Groups I and II read on patentably distinct inventions drawn to multiple polynucleotide and protein sequences. The claims encompass polynucleotides of SEQ I D NO: 1-40, polypeptides encoded by SEQ ID NO: 1-40 and antibodies to said polypeptides. Each polynucleotide, polypeptide and antibody constitutes a distinct chemical compound and each has a distinct functional property. In particular, each polynucleotide consists of a different nucleotide sequence, has a different melting temperature and a different specificity of hybridization. For example, a polynucleotide comprising SEQ ID NO: 1 is chemically, structurally and functionally distinct from an oligonucleotide comprising SEQ ID NO: 2. A search for a polynucleotide comprising SEQ ID NO: 1 would not be co-extensive with a search for an oligonucleotide comprising SEQ ID NO: 2. Further, a finding that a polynucleotide comprising SEQ ID NO: 1, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that a polynucleotide comprising SEQ ID NO: 2 is also novel and unobvious over the prior art. Similarly, a finding that a polynucleotide comprising SEQ ID NO: 1 is anticipated or obvious over the prior art would not necessarily extend to a finding that a polynucleotide comprising SEQ ID NO: 2 is also anticipated or obvious over the prior art. Similarly, each polypeptide and each antibody

consists of a different amino acid sequence, has a distinct biological activity, and a distinct binding activity.

Accordingly, the polynucleotides, polypeptides, and antibodies, and combinations thereof, are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, applicant should elect one sequence selected from the group consisting of SEQ ID NO: 1-40, or one combination thereof, OR, one protein encoded by the sequence of SEQ ID NO: 1-40 or one combination thereof, OR one antibody directed to a polypeptide encoded by one of SEQ ID NO: 1-40, or one combination thereof.

Sequence Election Requirement Applicable to Group V

4. If Applicant elects group V, Applicant must further elect a single gene product selected from the group of gene products set forth in claim 19. Each of the recited gene products is patentably distinct in that each gene product consists of a different amino acid sequence and has a unique functional activity. A search for each of the individual protein products would not be co-extensive with one another and undue burden would be required to search each of the gene products. Thereby, methods which use each of these gene products to diagnose lung cancer are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and not an election of species.

5. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, a search for inventions I-XI requires different keyword and sequence database searches that are not co-extensive. For example, a search for the nucleic acids of invention I would require different keyword and sequence searches as compared to a search for the proteins and antibodies of inventions II and III or the methods of inventions IV-XI. Additionally, a finding that the product of invention I is novel and unobvious would not necessarily extend to a holding that the products and methods of inventions II-XI are also novel and unobvious. Similarly, a search indicating that the products of invention I were known or would have been obvious would not necessarily extend to a holding that the products and methods of inventions II-XI were also known and obvious. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

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PRIMARY EXAMINER